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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/687,081 | 10/15/2003 | Mark E. Deem | 38349-0103K (17075-004011) | 9093 |
| 20985 | 7590 | 01/24/2005 | EXAMINER | |
| FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081 | | | LEWIS, AARON J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,081

Applicant(s)

MARK E. DEEM ET AL.

Examiner

AARON J. LEWIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-12 and 15-18 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 13 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-4,7-12,15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Alferness et al. ('951).

As to claim 1, Alferness et al. disclose a method of restricting fluid flow through a bronchial passageway in a patient's lung comprising: providing a flow control element (90,100) comprising a plurality of leaflets (#94 of figs.11-13 and col.6, line 44-col.7, line 13) movable from a closed position to an open position, the leaflets each having a distal surface, a proximal surface opposite the distal surface, and an engagement surface (i.e. surfaces adjacent slits 104,122), the engagement surfaces of the leaflets engaging each other in the closed position (e.g. fig.12), positioning the flow control element through the

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patient's trachea into the bronchial passageway (figs.2,5-7 and col.5, lines 33-42; col.6, lines 8-15), and anchoring (col.5, lines 48-50) the flow control element within the bronchial passageway, wherein the proximal surfaces of the leaflets are engaged by fluid when the patient inhales to urge the engagement surfaces into engagement with each other to maintain the leaflets in the closed position (col.6, line 47-col.7, line 13).

As to claim 2, Alferness et al. disclose the distal surfaces are engaged by fluid when the patient exhales to move the leaflets to the open position (col.6, line 47-col.7, line 13).

As to claim 3, Alferness et al. disclose the engagement surface of each leaflet comprises a portion of the distal surface of the leaflet. That is, at least a portion of the distal surface is adjacent slit 104, 122 in the valve.

As to claim 4, Alferness et al. disclose the engagement (at slit 104,122) of the leaflets with each other prevents the leaflets from opening when the patient inhales (col.6, line 47-col.7, line 13).

As to claim 7, Alferness et al. disclose the flow control element is positioned through the patient's trachea in a collapsed configuration, the anchoring step comprising expanding an expandable portion of the flow control element to an expanded configuration to engage a wall of the bronchial passageway (col.5, lines 48-50).

As to claim 8, Alferness et al. disclose the flow control element comprises a stent, the stent being expanded during the step of anchoring (col.5, lines 48-50).

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Claims 9-12,15-18 are substantially equivalent in scope to claims 1-4,7,8 and are anticipated by Alferness et al. for the reasons set forth above with respect to claims 1-4,7,8.

Allowable Subject Matter

3. Claims 5,6,13,14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

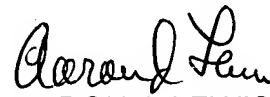
4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant methods for restricting fluid flow in a bronchial passageway in a patient's lung.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
December 12, 2004